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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/918,508	08/01/2001	Tatsuo Kakimoto	Q65478	3296

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EXAMINER

HUNNICUTT, RACHEL KAPUST

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 10/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/918,508	Applicant(s) KAKIMOTO ET AL.	
	Examiner Rachel K. Hunnicutt	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 9-19 and 22-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 20, 21, 28 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/02, 8/02, 11/01</u> . | 6) <input type="checkbox"/> Other: _____ |

RESPONSE TO AMENDMENT

Applicant's amendment filed July 6, 2004 is acknowledged. Claims 1-8, 20, and 21 are amended. Claims 28 and 29 are new. Claims 9-19 and 22-27 are withdrawn from consideration as being drawn to nonelected inventions. Claims 1-8, 20, 21, 28, and 29 are under consideration. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claim Rejections/Objections Withdrawn

The objection to the specification regarding embedded hyperlinks is withdrawn in response to Applicant's amendment to the specification.

The objection to the specification regarding the use of trademarks is withdrawn in response to Applicant's amendment to the specification.

The objection to the claim 8 regarding the misspelling of "cytokinin" is withdrawn in response to Applicant's amendment of claim 8.

The rejection of claim 2 under 35 U.S.C. 112, second paragraph is withdrawn in response to applicant's amendment of claim 2.

The rejection of claim 3 under 35 U.S.C. 112, second paragraph is withdrawn in response to applicant's amendment of claim 3.

The rejection of claim 4 under 35 U.S.C. 112, second paragraph is withdrawn in response to applicant's amendment of claim 4.

The rejection of claim 8 under 35 U.S.C. 112, second paragraph is withdrawn in response to applicant's amendment of claim 8.

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The rejection of claims 20 and 21 under 35 U.S.C. 112, second paragraph is withdrawn in response to applicant's amendments to claims 20 and 21.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 28 encompasses genes which hybridize under "stringent conditions" to polynucleotides consisting of SEQ ID NO: 1, 3, or 5. The term "stringent conditions" is a relative term which renders the claims indefinite. The term is not defined by the claim, and whereas the specification provides examples of stringent conditions (p. 16), the specification neither provides a definition of stringent conditions nor a standard for ascertaining the requisite degree, and one skilled in the art would not be reasonably apprised of the scope of the invention. It is unclear what amount hybridizing would occur under "stringent" conditions. One skilled in the art would not know what the metes and bounds of stringent conditions are.

The rejection of claim 8 under 35 U.S.C. 112, first paragraph, for lack of enablement is maintained for reasons of record on p. 4-5 of paper no. 1203. The rejection of claims 1-7 and 20-21 under 35 U.S.C. 112, first paragraph, for lack of enablement is withdrawn in view of Applicant's argument that the specification and art teach structural characteristics of cytokinin genes.

Applicants argue that the specification enables the full scope of the claims, because the specification describes the structural characteristics of cytokinin genes in the art. For example, Applicants refer to p. 23-25 of the specification as describing the structural characteristics of cytokinin genes.

Applicants' arguments have been fully considered but have not been found to be persuasive. The specification is not enabling for measuring the activity of "partially transmembrane region-deleted type cytokinin receptors", "chimera-type cytokinin" receptors, and cytokinin receptors having a plurality of amino acids deleted, substituted or added, which claim 8 encompasses. Applicants have not provided any functional or structural limitations for these variants of cytokinin receptors. In addition, Applicants have not taught what portions of the transmembrane domain or which amino acids may be deleted, substituted or added in order to yield a functional cytokinin receptor. The structural differences could be so great that these cytokinin receptor variants cannot promote the growth of lateral buds, stimulate chloroplast development, or delay senescence in leaves. One of skill in the art would not know how to use such cytokinin receptors if they do not have the same function as the cytokinin receptors identified in the current application.

Since detailed information regarding the structural requirements of the cytokinin receptor variants is lacking, the state of the prior art, the unpredictability of the art, the lack of working examples, the breadth of the claims, and the lack of direction provided by the Applicants, it would require undue experimentation by one of skill in the art to practice the invention as claimed without further guidance from the instant specification.

The rejection of claims 1, 3-8, 20, and 21 under 35 U.S.C. 112, first paragraph, as not being enabled for methods of analyzing agonist activity by measuring any intracellular signal transduction is maintained for reasons of record on p. 5-6 of paper no. 1203. New claims 28 and 29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of measuring agonist activity by measuring the quantity of cell growth of a transformed cell, does not reasonably provide enablement for methods of measuring the existence or quantity of any intracellular signal transduction.

Applicants argue that the examiner has mischaracterized the state of the art, and the specification provides sufficient guidance for determining cytokinin activity.

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Applicants argue that measuring histidine kinase activity is also enabled by the specification. In addition, Applicants refer to Inoue *et al.* (2001), *Nature* 409: 1060-1063, cited in the declaration filed under 37 CFR 1.131, which shows that the histidine kinase pathway is involved in transducing the intracellular signal for cytokinin receptors. Further, Applicants argue that Estelle (cited by the examiner in paper no. 1203) is not a good indication of the art because it was published in 1998 whereas the current application was filed in 2001.

Applicants' arguments have been fully considered and been found partially persuasive. Measuring histidine kinase activity is enabled by the specification and by the state of the art as a means for measuring cytokinin activity. In addition, on p. 28 of the specification Applicants teach the use of a two-component regulatory system for measuring signal transduction. However, the specification does not provide any other examples of signal transduction that may be measured, thus the specification does not provide enablement for measuring all types of intracellular signal transduction. One of skill in the art would not know what other responses to look for when analyzing agonist activity.

Claim Rejections - 35 USC § 103

The rejection of claims 1, 2, 6-8, 20 and 21 under 35 U.S.C. 103(a) as being unpatentable over Benfey *et al.* in view of Iawamura *et al.* is maintained for reasons of record on p. 6-8 of paper no. 1203. New claims 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benfey *et al.*, in view of Iwamura *et al.*

The examiner notes that Applicants have filed a declaration under 37 U.S.C. 1.131. If the declaration filed on July 6, 2004 were signed by all of the inventors, it would have been effective to overcome Benfey *et al.* However, the declaration was submitted unsigned, and thus it has been considered but is ineffective to overcome the Benfey *et al.* reference.

Benfey *et al.* teach WOL, which is nearly identical to one of the cytokinin receptors identified by Applicants as SEQ ID NO: 6 (also, see Rashotte *et al.* (2003), *Plant Physiology*, 132: 1998-2011 which teaches that the WOL gene is the same as

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CRE1, a cytokinin histidine kinase receptor). Thus, the protein as taught by Benfey *et al.* is within the scope of the claims. Benfey *et al.* teach plant cells transformed with recombinant constructs expressing the WOL gene (paragraph 0137). Furthermore, Benfey *et al.* teach identification of ligands to the WOL cytokinin receptor (paragraph 0151). Benfey *et al.* also teach that WOL is a two-component signal transducer. Moreover, Benfey *et al.* teach methods for identifying compounds that modulate the activity of a WOL polypeptide comprising contacting the polypeptide with a test compound and determining the effect of the test compound on the activity of the polypeptide (see claims 6 and 17 and paragraph 0121). Benfey *et al.* further teach that the WOL gene products may be expressed in yeast (page 12, paragraph 133), such as the budding yeast *Saccharomyces*. However, Benfey *et al.* do not teach a method for analyzing agonist activity wherein intracellular signal transduction is measured.

Iwamura *et al.* teach a method of exposing cells expressing cytokinin receptors to cytokinin receptor agonists and antagonists. Iwamura *et al.* further teach measuring cytokinin receptor activity by measuring the fresh weight yield of a tobacco callus, *i.e.* measuring cell propagation (p. 839). Thus, it would have been *prima facie* obvious to a person of ordinary skill in the art to modify the method as taught by Benfey *et al.* by measuring changes in signal transduction as taught by Iwamura *et al.* Motivation to do so is provided by Iwamura *et al.* in that they teach measuring the effects of agonists on cytokinin receptors, and the WOL gene as taught by Benfey *et al.* is a cytokinin receptor. One of ordinary skill in the art would have expected the modified method to work as well as the one exemplified.

Conclusion

NO CLAIMS ARE ALLOWED.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel K. Hunnicutt whose telephone number is (571) 272-0886. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RKH
9/30/04


JANET ANDRES
PRIMARY EXAMINER